

(d) Before consolidating a hearing, the ALJ must notify CMS of his or her intention to do so, and CMS may then elect to participate in the consolidated hearing by sending written notice to the ALJ.

(1) For non-expedited hearings, any request by CMS to participate must be made within 5 calendar days of receipt of the ALJ's notice of the consolidation.

(2) For expedited hearings, any request by CMS to participate must be made within 1 calendar day of receipt of the ALJ's notice of the consolidation. Requests may be made orally or submitted by facsimile to the hearing office.

(e) If the ALJ decides to hold a consolidated hearing, he or she may make either a consolidated decision and record or a separate decision and record on each issue. The ALJ ensures that any evidence that is common to all appeals and material to the common issue to be decided is included in the consolidated record or each individual record, as applicable.

§ 423.2046 Notice of an ALJ decision.

(a) *General rule.* Unless the ALJ dismisses the hearing, the ALJ will issue a written decision that gives the findings of fact, conclusions of law, and the reasons for the decision.

(1) For expedited hearings, the ALJ issues a written decision within the 10 calendar day adjudication timeframe under § 423.2016(b)(5).

(2) The decision must be based on evidence offered at the hearing or otherwise admitted into the record.

(3) A copy of the decision should be mailed to the enrollee at his or her last known address.

(4) A copy of the written decision should also be provided to the IRE that issued the reconsideration determination, and to the Part D plan sponsor that issued the coverage determination.

(b) *Content of the notice.* The decision must be provided in a manner calculated to be understood by an enrollee and must include—

(1) The specific reasons for the determination, including, to the extent appropriate, a summary of any clinical or

scientific evidence used in making the determination;

(2) The procedures for obtaining additional information concerning the decision; and

(3) Notification of the right to appeal the decision to the MAC, including instructions on how to initiate an appeal under this section.

(c) *Limitation on decision.* When the amount of payment for the Part D drug is an issue before the ALJ, the ALJ may make a finding as to the amount of payment due. If the ALJ makes a finding concerning payment when the amount of payment was not an issue before the ALJ, the Part D plan sponsor may independently determine the payment amount. In either of the aforementioned situations, an ALJ's decision is not binding on the Part D plan sponsor for purposes of determining the amount of payment due. The amount of payment determined by the Part D plan sponsor in effectuating the ALJ's decision is a new coverage determination under § 423.566.

(d) *Timing of decision.* For non-expedited hearings, the ALJ issues a decision no later than the end of the 90 calendar day period beginning on the date the request for hearing is received by the entity specified in the IRE's reconsideration, unless the 90 calendar day period is extended as provided in § 423.2016. For expedited hearings, the ALJ issues a decision as expeditiously as the enrollee's health condition requires, but no later than the end of the 10 calendar day period beginning on the date the request for hearing is received by the entity specified in the IRE's reconsideration, unless the 10 calendar day period is extended as provided in § 423.2016.

(e) *Recommended decision.* An ALJ issues a recommended decision if he or she is directed to do so in a MAC remand order. An ALJ may not issue a recommended decision on his or her own motion. The ALJ mails a copy of the recommended decision to the enrollee at his or her last known address.

§ 423.2048 The effect of an ALJ's decision.

The decision of the ALJ is binding unless—

§ 423.2050

(a) An enrollee requests a review of the decision by the MAC within the stated time period or the MAC reviews the decision issued by an ALJ under the procedures set forth in § 423.2110, and the MAC issues a final decision or remand order;

(b) The decision is reopened and revised by an ALJ or the MAC under the procedures explained in § 423.1980;

(c) The expedited access to judicial review process at § 423.1990 is used;

(d) The ALJ's decision is a recommended decision directed to the MAC and the MAC issues a decision; or

(e) In a case remanded by a Federal District Court, the MAC assumes jurisdiction under the procedures in § 423.2138 and the MAC issues a decision.

§ 423.2050 Removal of a hearing request from an ALJ to the MAC.

If a request for hearing is pending before an ALJ, the MAC may assume responsibility for holding a hearing by requesting that the ALJ send the hearing request. If the MAC holds a hearing, it conducts the hearing according to the rules for hearings before an ALJ. Notice is mailed to the enrollee at his or her last known address informing him or her that the MAC has assumed responsibility for the case.

§ 423.2052 Dismissal of a request for a hearing before an ALJ.

Dismissal of a request for a hearing is in accordance with the following:

(a) *Dismissal of a request for a hearing.* An ALJ dismisses a request for a hearing under any of the following conditions:

(1) At any time before notice of the hearing decision is mailed, if the enrollee asks to withdraw the request. This request may be submitted in writing to the ALJ or be made orally at the hearing. The request for withdrawal must include a clear statement that the enrollee is withdrawing the request for hearing and does not intend to further proceed with the appeal. If an attorney or other legal professional on behalf of an enrollee files the request for withdrawal, the ALJ may presume that the representative has advised the enrollee of the consequences of the withdrawal and dismissal.

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(2) Neither the enrollee that requested the hearing nor the enrollee's representative appears at the time and place set for the hearing, if—

(i) The enrollee was notified before the time set for the hearing that the request for hearing might be dismissed without further notice for failure to appear; or

(ii) The enrollee did not appear at the time and place of hearing and does not contact the ALJ hearing office within 10 calendar days for non-expedited hearings and 2 calendar days for expedited hearings and provide good cause for not appearing; or

(iii) The ALJ sends a notice to the enrollee asking why the enrollee did not appear; and the enrollee does not respond within 10 calendar days for non-expedited hearings; the ALJ does not receive the enrollee's response within 2 calendar days for expedited hearings or the enrollee does not provide good cause for the failure to appear. For expedited hearings, an enrollee may submit his or her response orally to the ALJ.

(iv) In determining whether good cause exists under paragraph (a)(2) of this section, the ALJ considers any physical, mental, educational, or linguistic limitations (including any lack of facility with the English language) the enrollee may have.

(3) The person requesting a hearing has no right to it under § 423.2002.

(4) The enrollee did not request a hearing within the stated time period and the ALJ has not found good cause for extending the deadline, as provided in § 423.2014(d).

(5) The enrollee died while the request for hearing is pending and the request for hearing was filed by the enrollee or the enrollee's representative, and the enrollee's surviving spouse or estate has no remaining financial interest in the case and the enrollee's representative, if any, does not want to continue the appeal.

(6) The ALJ dismisses a hearing request entirely or refuses to consider any one or more of the issues because an IRE, an ALJ or the MAC has made a previous determination or decision under this subpart about the enrollee's rights on the same facts and on the